REMARKS/ARGUMENTS

Present Invention and Pending Claims

Claims 1-8 and 15-17 are pending. Claims 1-8 are directed to a pharmaceutical composition. Claims 15-17 are directed to a method of treating a cardiovascular disorder.

Amendments to the Claims

Claims 3 and 5 have been amended to delete the term "substantially" and to recite that the amount of inhibitor in crystalline form is more than 50%. Claims 4 and 6 have been amended to recite that the amount of cholesterol ester transfer protein inhibitor in amorphous form does not exceed about 10%. The amendments to claims 3-6 are supported by the specification at, for example, paragraph 0078 of the originally filed specification (which corresponds to paragraph 0079 of the substitute specification). No new matter has been added by way of these amendments.

Amendment of Inventorship

A request to amend inventorship was filed on April 5, 2011, in the present application, which seeks to delete Masaki Sunami and Takanori Serigano as inventors, and to add Yoshifumi Uemoto, who was not originally named as an inventor, as the sole inventor on the present application. The Examiner is requested to acknowledge and enter the inventorship correction request.

Summary of the Office Action

Claims 3-8 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 1-8 and 15-17 have been rejected under 35 U.S.C. § 103(a), as allegedly obvious over Ault et al. (U.S. Patent Application Publication 2002/0123459) in view of Curatolo et al. (WO 2002/011710).

Claims 1-8 and 15-17 have been rejected on the grounds of obviousness-type double patenting over claims 1-6, 10, 11, 16-21, 34-40, and 53-58 of U.S. Patent 7,276,536 (Urata et al.) (hereinafter "the '536 patent") in view of Ault et al. and Curatolo et al.

Reconsideration of the pending claims is hereby requested.

Discussion of the Indefiniteness Rejection

Claims 3-8 allegedly are indefinite because of the term "substantially."

To expedite prosecution, and not in acquiescence of the rejection, claims 3 and 5 have been amended to delete the term "substantially," thereby rendering the indefiniteness rejection moot. Moreover, claims 3 and 5 have been amended to recite that the amount of inhibitor in crystalline form is more than 50%. Claims 4 and 6 have been amended to recite that the amount of cholesterol ester transfer protein inhibitor in amorphous form does not exceed about 10%.

Since amended claims 3-8 clearly establish the metes and bounds of the amount of the crystalline or amorphous form of the inhibitor, Applicant respectfully requests the withdrawal of the indefiniteness rejection.

Discussion of the Obviousness Rejection

Claims 1-8 and 15-17 allegedly are obvious over Ault et al. in view of Curatolo et al.

As previously discussed in the "Reply to Office Action" dated April 5, 2011, Ault et al. discloses a solid pharmaceutical composition for oral delivery comprising an active agent, crospovidone or povidone, and a delivery agent for the active agent. Ault et al. also discloses solid pharmaceutical compositions comprising calcitonin and either crospovidone or povidone. Ault et al. reportedly describes that the composition comprising crospovidone versus compositions without crospovidone provided enhanced bioavailability of calcitonin (col. 9, lines 34-38). The Office concedes that Ault et al. does not disclose increasing the bioavailability of JTT-705 (a CETP inhibitor).

Curatolo et al. allegedly discloses various CETP inhibitors in amorphous and crystalline form, including JTT-705. Curatolo et al. allegedly further discloses that CETP inhibitors have extremely low solubility and thus have low oral bioavailability.

According to the Office, one of ordinary skill in the art would have been motivated to substitute the active agent of Ault et al. with JTT-705. One of ordinary skill in the art

supposedly would have had a reasonable expectation of success in increasing the bioavailability of JTT-705 because Ault et al. discloses that "crospovidone is known to achieve a great enhancement in oral bioavailability" (Office Action, page 6, first full paragraph).

Applicant traverses the obviousness rejection based on the following discussion.

For subject matter defined by a claim to be considered obvious, the Office must demonstrate that the differences between the claimed subject matter and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); see also *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The ultimate determination of whether an invention is or is not obvious is based on certain factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, (3) the differences between the claimed invention and the prior art, and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467.

Applicant maintains that the Office has failed to set forth a proper *prima facie* case of obviousness because the Office has failed to properly determine the scope and content of the prior art (i.e., element (1) of the *Graham* factors set forth above). In particular, the Office has mischaracterized the disclosure of Curatolo et al. such that the basis of the obviousness rejection is in error. According to the Office Action, Curatolo et al. discloses that "the *amorphous* form [of the CETP inhibitor] does not exceed 25 percent (page 9)" (Office Action at sentence bridging pages 5 and 6 (emphasis added)). However, at page 9, lines 18-20, Curatolo et al. states: "As used herein, 'substantially amorphous' means that the amount of the CETP inhibitor in *crystalline* form does not exceed about 25%." (emphasis added). This discrepancy between the remarks in the Office Action and the disclosure of Curatolo et al. evidences that the Office has improperly construed the disclosure of Curatolo et al. As a result, the basis of the obviousness rejection is faulty such that a proper *prima facie* case of obviousness based on the combination of Ault et al. and Curatolo et al. has not been established by the Office.

Since a proper *prima facie* case of obviousness has not been established, the obviousness rejection of claims 1-8 and 15-17 must be withdrawn.

Discussion of the Obviousness-type Double Patenting Rejection

Claims 1-8 and 15-17 have been rejected on the grounds of obviousness-type double patenting over certain claims of the '536 patent in view of Ault et al. and Curatolo et al.

The Office fails to set forth a proper *prima facie* case of obviousness-type double patenting for the following reasons.

The Office does not recite the scope of claims 1-8 and 15-17 nor make a comparison between the elements of claims 1-8 and 15-17 and the claims of the '536 patent. In particular, the similarities and differences between pending claims 1-8 and 15-17 and the cited claims of the '536 patent are not set forth in the Office Action.

The Office also does not set forth a credible reason as to why one of ordinary skill in the art would turn to Ault et al. and/or Curatolo et al. after considering the claims of the '536 patent. As noted by the Office, the claims of the '536 patent are directed to increasing the bioavailability of JTT-705. Both Ault et al. and Curatolo et al. similarly are directed to a means of increasing the bioavailability of an active agent (e.g., calcitonin or a CETP inhibitor). The Office does not provide a credible reason for one of ordinary skill in the art to have considered the disclosures of Ault et al. and Curatolo et al. for *additional* methods of increasing the bioavailability of JTT-705 when the claims of the '536 patent already recite a solution to such a problem.

Furthermore, as discussed above, Applicant maintains that the Office has mischaracterized the disclosure of Curatolo et al. in the Office Action. In particular, the Office alleges that Curatolo et al. discloses that "the *amorphous* form [of the CETP inhibitor] does not exceed 25 percent (page 9)" (Office Action at page 8, first paragraph (emphasis added)). However, Curatolo et al. actually states: "As used herein, 'substantially amorphous' means that the amount of the CETP inhibitor in *crystalline* form does not exceed about 25%." (page 9, lines 18-20 (emphasis added)).

Since a proper *prima facie* case of obviousness-type double patenting has not been established, the obviousness-type double patenting rejection of claims 1-8 and 15-17 must be withdrawn.

Conclusion

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

Respectfully submitted,

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